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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,063

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Aharon Hazut

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Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

MCEVOY, THOMAS M

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,063	Applicant(s) HAZUT ET AL.	
	Examiner THOMAS MCEVOY	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,14-24 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,14-24 and 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/2011, 2/1/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 20th 2011 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17, 22 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 recites "injecting an aqueous solution into the pigmented section prior to or during the puncturing of the skin". Claims 31 and 32 recite "injecting an aqueous solution into the pigmented section before or during the puncturing of the skin". Examiner does not see where injecting prior to puncturing is disclosed. Applicant has stated in the response that this is disclosed in paragraphs 0021 and 0032 of the published application. These

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paragraphs appear to only disclose that the puncturing device needle is dipped in the aqueous solution prior to puncturing. The injecting step appears to only be possible if performed simultaneously with puncturing as disclosed. Claims 17, 22, 29 and 30 require the pigments to be absorbed within a period less than 20 minutes or an hour or the pad to be removed within 20 minutes. These limitations are only disclosed when using saline; not a salt-based granular paste.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 9, 14-18, 21, 23, 24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943).

Regarding claims 1, 5 and 9 Malodobry discloses a method for removing pigments from a pigmented section of skin, comprising: a) puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one solid needle, thereby liberating the pigments and cellular fluids from cells containing said pigments (paragraphs 0043-0048). Malodobry fails to explicitly state that pigments are liberated from within cells in regards when using his method. However, Malodobry clearly discloses that the pigments reside within intact cells (paragraph 0035) and goes on to

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give an example of how the diathermy technique is used to liberate pigments from these intact cells (paragraph 0035). Therefore, it would have been obvious to one of ordinary skill in the art to have used the Malodobry puncturing step to liberate pigments from within cells as claimed since Malodobry discloses that pigments reside within cells. Malodobry fails to disclose b) bandaging said punctured skin with a pad adapted to absorb said pigments and said cellular fluids, said pad containing one or more materials capable of accelerating a process of migration of said pigments toward an outer layer of the skin, wherein said one or more materials is a salt-based granular paste. Malodobry does disclose using irritants such as sodium chloride to increase exudate and thereby increase the amount of pigments migrating towards the outer layer (this is clearly the intent of using irritants as disclosed in paragraphs 0050-0052; Examiner notes that the use of irritants is disclosed immediately after Malodobry discloses an intent to use wound exudate to carry pigments to the skin surface; see paragraph 0049). Bogart et al. disclose bandaging a wound with a pad (col. 9, lines 31-35; col. 3, lines 49-54) containing a sodium chloride based granular (col. 4, lines 42-46) paste (a granular gel can be considered as a paste; Applicant has provided experimental data which disclosed the paste as KY gel and salt) to accelerate a process of skin exudate and bacteria migration to an outer layer of skin (col. 4, lines 60-63; col. 9, lines 44-60). It would have been obvious to one of ordinary skill in the art in view of Bogart et al. to have used a pad and paste as claimed for a number of reasons. For example, Malodobry suggests using a sodium chloride irritant but does not give a specific method for applying it. The device and method of Bogart et al. would provide one of ordinary

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skill in the art with a specific device and method for implementing Malodobry's suggestion of using a sodium chloride irritant to increase wound exudate or drainage. One of ordinary skill in the art would also recognize that the device and method of Bogart et al. would especially enable the exudate to carry the pigments as intended by Malodobry because Bogart et al. teach that their method would cause exudate to sweep bacteria to the outer layer and bacteria can be as large or larger than the pigment agglomerates. One of ordinary skill in the art would at least be motivated to apply the method of Bogart et al. to heal the wound of Malodobry after the pigments are substantially removed. The step(s) provided by Bogart et al. could still be considered as part of the overall method of pigment removal. Regarding claims 2 and 15, Bogart et al. further teach applying one or more antiseptic materials to the punctured skin via the paste (col. 6, lines 27-28 and elsewhere). Regarding claim 3, the paste of Bogart et al., containing the antiseptic materials, can be applied with a pad as explained above. Regarding claim 4, the skin-puncturing device of Malodobry is a tattooing device (paragraph 0046). Regarding claims 14, 31 and 32, Malodobry discloses injecting aqueous irritant into the pigmented section as claimed (paragraphs 0050 and 0052). It would have been obvious to one of ordinary skill in the art to have maintained this step when modifying with Bogart et al. because one of ordinary skill in the art would recognize that this step could further help the process of pigment migration in addition to the modification described above. Regarding claim 16, Bogart et al. teach impregnating the pad with the gel (col. 3, lines 49-54) as well as providing antibiotics within the gel as described above. Regarding claims 17, 28, 29 and 30, it would have

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been obvious to one of ordinary skill in the art to have modified the gel/paste in order to absorb within the time period as claimed because 1) both Malodobry and Applicant use the same method for creating the wound which should produce a comparable amount of exudate or drainage within a comparable amount of time and 2) Bogart et al. teach absorbing the exudate into the pad/paste as it comes out of the wound (col. 9, lines 31-40). Secondly, since Applicant has not disclosed a specific formulation of the paste (a specific formulation for saline is disclosed that produces a timed effect) that produces the claimed timed effect, it is concluded that any salt-based granular paste must be capable of absorbing pigments within the claimed times. Therefore, Malodobry in view of Bogart et al. disclose these limitations. Furthermore, Bogart et al. disclose bandaging the wound with a pad impregnated with the paste (col. 3, lines 43-53; col. 13, lines 4-6). Regarding claim 18, Malodobry discloses that the needle is hollow (paragraph 0043). Regarding claim 21, it would have been obvious to one of ordinary skill in the art to have not provided tattooing ink with the tattooing device in the above method because the method is intended to remove ink already present in the skin. Regarding claim 23, Bogart et al. teach that the pad should be designed to hold exudate away from the wound (col. 9, lines 36-38). Therefore, it would have been obvious to one of ordinary skill in the art to have removed the pad prior to complete saturation in order to prevent excess exudate from leaking out of the pad and on or around the wound. Furthermore, it would have been obvious to one of ordinary skill to remove the pad prior to saturation in order to prevent the pad from leaking fluid onto a patient. Regarding claim 24, Bogart et al. teach securing an absorbent dressing or pad (col. 9, lines 31-34; col. 10, lines 46-

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49). It is old and well-known in the art that absorbent pads are typically applied by wrapping or securing an absorbent pad to a wound with gauze or medical tape.

Therefore, it would have been obvious to one of ordinary skill in the art to have secured an absorbent dressing or pad to the wound using by wrapping or covering the pad with gauze or medical tape. Regarding claim 27, Bogart et al. teach removing the pad after draining a sufficient amount of exudate and then applying a second pad to promote healing as explained above. Bogart et al. also teach applying antibiotics as explained above. It would therefore have been obvious to one of ordinary skill in the art to have provided antibiotics on the second pad because they would promote healing by reducing the chance of infection.

5. Claims 6, 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Garitano et al. (US 2004/0158196).

Regarding claims 6, 7, 19 and 20, Malodobry in view of Bogart et al. disclose the invention as described above. They do not disclose performing the suction of the pigments from said punctured skin with the suction means prior to the bandaging of the punctured skin and during the puncturing of said skin. Garitano teaches the suction of a solution provided for the removal of tattoos (paragraph 0023). Performing this step during the puncturing step would have been obvious to a person having ordinary skill in the art because prior to this step, there is no fluid to be suctioned. Also, performing this step prior to bandaging would have been obvious because after bandaging, the suction step would not be easily performed. Furthermore, the Examiner notes that no specific

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advantage was provided for the ordering of these steps so it is considered within the purview of one having ordinary skill in the art to rearrange the order of steps (see MPEP 2144.04 IV C). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the Malodobry removal steps to include Garitano's suction step. Such a modification would draw fluid from the tattoo to further aid in the removal of the pigments. Since Malodobry discloses that the needles used to perform the puncturing are capable of suctioning liquids (paragraph 0043), it would have been obvious to modify the puncturing device to be capable of suctioning in order to apply the Garitano teaching. Malodobry further discloses that other prior art methods of pigment removal should also be used simultaneously (paragraph 0053).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Dosch et al. (US 7,012,096 B2).

Regarding claim 22, it would have been obvious to one of ordinary skill to remove the pad before damaging the skin. Bogart et al. disclose using any gelling agent for their invention. Dosch et al. disclose a gelling agent composition suitable for pain mediation of wounds (claim 9) which can be applied for 20 minutes (col. 12, lines 23-25) and other short periods. Therefore, it would have been obvious to one of ordinary skill in the art to have used the gelling agent composition of Dosch et al. with the paste of Bogart et al. in order to sooth pain and to have applied the paste for 20 minutes or less.

Response to Arguments

7. Applicant's arguments, including the Affidavit, filed January 20th 2011, have been considered but are not persuasive. Applicant has argued that it is not proper to combine the method of Bogart et al. with the method of Malodobry because the method of Bogart et al. prevents the formation of a scab and the method of Malodobry requires the formation of a scab. Examiner does not see where Malodobry requires the formation of a scab. It is given as just one example for how the pigments are removed from the surface after migration. Applicant has argued that Malodobry only suggests the use of dilute suspensions of irritants. Malodobry discloses that the irritants can be solid and even discloses solid NaCl as a filler (paragraphs 0050-0052). Applicant's argument in regard to Dosch et al. has been addressed by the new section cited above. The remainder of Applicant's arguments have been addressed in the previous office action of record.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773